

## CERTIFICATE OF ANALYSIS

Product: **TADALAFIL**

Code: **QTDF-0008-000** Batch number: **106022527** Batch size: **10 kg**  
 Manufacturing date: **10.02.2025** Analysis date: **06.03.2025** Retest date: **02.2028**  
 Manufacturer: **Zakłady Farmaceutyczne POLPHARMA S.A., POLAND**  
 Delivered to: **IT, A.C.E.F. SPA**

TEST	TEST METHOD	SPECIFICATION	RESULTS
<b>Appearance</b>	visual examination	white or almost white powder	white powder
<b>Solubility</b>	Ph. Eur.	practically insoluble in water, freely soluble in dimethyl sulfoxide, slightly soluble in methylene chloride	conforms
<b>Identification: Tests A, B</b>			
A. IR spectrum	Ph. Eur.	corresponds to reference substance spectrum	conforms
B. HPLC	Ph. Eur.	the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a)	conforms
<b>Impurities A, B and C (HPLC)</b>			
impurity A	Ph. Eur.	not more than 0.15 %	less than 0.05 %
unspecified impurities		not more than 0.10 %	less than 0.05 %
<b>Related substances (HPLC)</b>			
unspecified impurities	Ph. Eur.	not more than 0.10 %	less than 0.05 %
total		not more than 0.3 %	less than 0.05 %
<b>Loss on drying</b>	Ph. Eur.	not more than 0.5 %	0.09 %
<b>Sulfated ash</b>	Ph. Eur.	not more than 0.1 %	0.02 %
<b>Assay calculated on the dried substance (HPLC)</b>	Ph. Eur.	97.5 % to 102.0 %	100.1 %
<b>Content of methylamine (IC):</b>	POLPHARMA		
methylamine	M/2-0149.09	not more than 500 ppm	less than 25 ppm (DL)
<b>Residual solvents <sup>1)</sup>:</b>			
ethanol	Ph. Eur.	loss on drying: not more than 0.5 %	0.09 %

<sup>1)</sup> Ethanol belongs to 3 Class of solvents acc. Ph. Eur. and is tested by "Loss on drying" test acc.to Ph. Eur.- not more than 0.5%.

**CONCLUSION:** This material complies with the requirements of the **Ph. Eur., S/2-0149.12 ed. 02.**

Starogard Gdański, 07.03.2025

Head of Certification Team  
Quality Control Unit API

*Beata Wielewicka*  
**Beata Wielewicka**  
*07.03.2025*

Page 1 of 1